K053225

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510(k) Summary
As Required by 21 section 807.92 (c)

NOV - 6 2006

1-Submitter Name: LPG One, Inc
2-Address: 801 Brickell Ave. Suite 850. Miami, FL 33131
3-Phone: (305) 379- 8800
4-Fax: (305) 375- 0903
5-Contact Person (Consultant): Jay Mansour of Mansour Consulting LLC
845 Aronson Lake Court
Roswell, GA 30075 USA
(678) 908-8180. Fax (678) 623-3765
6-Date summary prepared: September 16th, 2006
7-Device Trade or Proprietary Name: CELLU M6 KEYMODULE i
8-Device Common or usual name: Massager
9-Device Classification Name: Electrical Therapeutic Massager
10-Substantial Equivalency is claimed against the following devices:

1- LPG One (formerly LPG USA) ES1 Massager- 510k #K990445
2- Shepard Medical's Sport Pump- 510k #K912004
3- Progressive Medical's Multipulse Sequential Compression unit- 510k #K914774
4- Grad-Line's Atlant's- 510k #K974395
5- Model SC-3008 Sequential Circulator- 510k #K043423
6- Flexitouch (also known as Biotouch)- 510k #K013061

11-Description of the Device:

The Cellu M6 Keymodule i electrical therapeutic massager is comprised of a program console housing a vacuum pump and a regulation system. The main treatment head i50 consists of two parallel motorized rollers housed in a chamber which produces both negative pressure above the rollers and positive pressure below the rollers. This technology creates a skin fold between the two rollers in a suction chamber, thus mimicking the "rolled palpation" of manual massage techniques.

In addition to Head i50 which is meant primarily for the upper arm and for legs, auxiliary heads T615, T615-A, T630, T630-A, T644 and T644-A are also used, as they better suit smaller morphology (parts) of the body. Details are provided along the labeling provided.

This device has the capability to produce both constant and sequential aspiration. Constant aspiration provides a deeper massage, which also mobilizes the muscle fascia. With sequential aspiration, the suction power is cyclically interrupted to provide pulsation to the skin fold between the two rollers and a softer, gentler stroking action of the tissues.

The suction power ranges from 45 mm Hg to 180 mmHg, which is represented by a power level scale ranging from 1 to 4.

12-Intended use of the device: (refer to FDA form attached)

The intended uses of this device are:

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Reduction of secondary lymphedema of the Arm (SLA) Post Mastectomy
Improvement of secondary lymphedema
Improvement of lymphatic circulation in the treated area

13-Safety and Effectiveness of the device:

This device is safe and effective as the predicate devices cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SUBSTANTIALLY EQUIVALENT** to the predicate devices. Refer to the explanations/details within the main submission.

FDA file reference number	510k # K912004, K914774, K974395, K043423 and K013061	510k #K990445
TECHNOLOGICAL CHARACTERISTICS	**Comparison result of this device with the predicate devices**	
Indications for use	Identical	Different
Target population	Identical	Different
Design	Similar in terms of mode of action	Very similar
Materials		
Performance		
Sterility	Not applicable	
Biocompatibility	Similar	
Mechanical safety		
Chemical safety	Not applicable	
Anatomical sites	Similar	Similar
Human factors		Similar
Energy used and/or delivered		Very similar
Compatibility with environment and other devices		Identical
Where used		Similar
Standards met		Very similar
Electrical safety		Very similar
Thermal safety	NOT APPLICABLE	
Radiation safety		

Refer to the submission for more details.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

LPG One, Inc.
C/o Jay Mansour, MSQA, BE, RAC
President, Mansur Consulting, LLC
845 Aronson Lake Court
Roswell, GA 30075

NOV - 6 2006

Re: K053225
Trade/Device Name: Cellu M6 Keymodule i
Regulation Number: 21 CFR 890.5665
Regulation Name: Therapeutic Massager
Regulatory Class: 21 CFR 890.9 - Limitations of exemptions from section 890.5660 - Class I
Product Code: ISA - IRO
Dated: June 23, 2006
Received: July 3, 2006

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

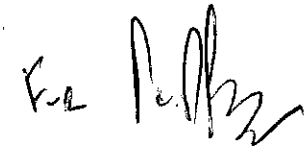
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson, M.S.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- 410 DGRND
D.O.

f/t: DXV: 10- 31-06

Indications for Use

510(k) Number (if known): K053225

Device Name: CelluM6 Keymodule i

Indications For Use:

Reduction of Secondary Lymphedema of the Arm (SLA) Post Mastectomy
Improvement of Secondary Lymphedema
Improvement of lymphatic circulation in the treated area

Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative, Page 1 of 1
and Neurological Devices

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